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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,684	10/27/2003	Tetsuya Suga	242791US0CONT	2064
22850	7590	10/30/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER GEORGE, KONATA M	
			ART UNIT	PAPER NUMBER
			1616	
			NOTIFICATION DATE	DELIVERY MODE
			10/30/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/692,684	<b>Applicant(s)</b> SUGA ET AL.	
	<b>Examiner</b> KONATA M. GEORGE	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 12-17, 19-36, 38-46, 48-53 and 75-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 12-17, 19-36, 38-46, 48-53 and 75-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/25/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1, 12-17, 19-36, 38-46, 48-53 and 75-78 are pending in this application.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on June 25, 2008 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Action Summary***

Any rejections of record that are not repeated below are considered withdrawn.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 12-17, 19-36, 38-46, 48-53 and 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kropf et al. (WO 00/54741) as translated by Kropf et al. (US 6,858,214).**

Applicants claim a composition comprising superfine particles beta-glucan derived from water extract of a mushroom having an average particle size of 10 microns or less.

***Determination of the scope and content of the prior art***  
**(MPEP §2141.01)**

Kropf et al. disclose the use of nanoscalar water-soluble  $\beta$ -glucans. The  $\beta$ -glucans are contained in cosmetic and/or pharmaceutical preparation having particle diameters in the range of 10 to 300 nm (equivalent to 0.01 to 0.30  $\mu$ m) (col. 1, lines 43-47). Column 1, lines 61-62 disclose a good source for the  $\beta$ -glucans, are yeast, from the *Sacchaomyces* family. Column 2, lines 10-37 disclose a process of producing the particles comprising dissolving the  $\beta$ -glucans under supercritical conditions in a suitable solvent, relaxing the fluid mixture through a nozzle in a vacuum, a gas or liquid, and at the same time evaporating the solvent. To prevent the particles from agglomeration the starting materials should be dissolved in the presence protective colloids or emulsifiers. The composition can further contain adjuvants known in the cosmetic and/or pharmaceutical industry (col. 3, lines 19-34). Column 5, lines 51-52 teach that lecithin can be used in the composition as a hyperfating agent.

***Ascertainment of the difference between the prior art and the claims***  
**(MPEP §2141.02)**

Kropf et al. do not teach that the beta-glucan particles are derived from a water extract of a mushroom.

***Finding of prima facie obviousness***  
***Rational and Motivation (MPEP §2142-2143)***

Where claims are directed to a composition, the manner by which the individual components are obtained is not a patentable distinction if the resulting composition is the same as taught in the prior art. The claim is to a composition and not a method of making the composition. Where claims are directed to a composition, the manner by which the individual components are made is not a patentable distinction if the resulting composition is the same as taught in the prior art. The claim is to a composition and not a method of making the composition. Therefore, any method of obtaining the beta glucan would have been obvious to one of ordinary skill in the art at the time of the invention.

***Response to Arguments***

Applicant's arguments filed June 25, 2008 have been fully considered but they are not persuasive.

Applicants argue that the beta-1,3-glucans of yeast does not comprise beta-1,6-glucans whereas beta-1,3-glucans derived from mushrooms comprises beta-1,6-glucans. Applicant provides several references to support the assertion. In a review of the references supplied, it is agreed that beta-1,3-glucans derived from mushrooms contains beta-1,6-glucans. However, applicant has not provided a reference document which teach that the beta-1,3-glucans derived from yeast are devoid of beta-1,6-glucans. Therefore, it is the position of the examiner that the beta glucans of Krpof et al. continue to read on the claimed invention.

**Claims 1, 12-17, 19-36, 38-46, 48-53 and 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostroff et al. (US 2005/0245480).**

Applicants claim a composition comprising superfine particles beta-glucan derived from water extract of a mushroom having an average particle size of 10 microns or less.

***Determination of the scope and content of the prior art***  
**(MPEP §2141.01)**

Ostroff et al. disclose the use of particulate, bioavailable  $\beta$ -glucan, wherein the particle is a microparticle having a particles size of 1 micron or less (paragraphs [0009-0010]). Paragraph [0017] discloses a method of preparing the  $\beta$ -glucan particles by a method of finely grinding yeast cell walls. Paragraph [0036] discloses a process for producing  $\beta$ -glucan particles involving an extraction and purification of the alkali-insoluble  $\beta$ -glucan particles from yeast or fungal membranes. Paragraph [0030] also discusses oral anti-infective and radiochemoprotective activities of  $\beta$ -glucan derived from mushrooms and yeast.

***Ascertainment of the difference between the prior art and the claims***  
**(MPEP §2141.02)**

Ostroff et al. do not teach that the beta-glucan particles are derived from a water extract of a mushroom.

***Finding of prima facie obviousness***  
***Rational and Motivation (MPEP §2142-2143)***

Where claims are directed to a composition, the manner by which the individual components are obtained is not a patentable distinction if the resulting composition is the same as taught in the prior art. The claim is to a composition and not a method of making the composition. Where claims are directed to a composition, the manner by which the individual components are made is not a patentable distinction if the resulting composition is the same as taught in the prior art. The claim is to a composition and not a method of making the composition. Therefore, any method of obtaining the beta glucan would have been obvious to one of ordinary skill in the art at the time of the invention.

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### ***Conclusion***

Claims 1, 12-17, 19-36, 38-46, 48-53 and 75-78 remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George  
Patent Examiner  
Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616